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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,663	06/25/2003	Pierre Charneau	03495.0199-01	8007

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,663	CHARNEAU ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-61* is/are pending in the application.

4a) Of the above claim(s) *52-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-51* is/are rejected.

7)☒ Claim(s) *41 and 46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/4/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 22 February 2006. Applicant elects Group I, claims 41-51, with traverse.

The traversal is on the grounds that there is no serious burden in examining the different Groups of Inventions together. Applicant's traversal is unpersuasive because while a search of the prior art for one Group may overlap with that of another Group, the searches are not co-extensive due to the distinctiveness of each Group as indicated in the prior Office Action, and thus would be an undue burden on Office resources.

The restriction among the different products that may be used in the claimed methods is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 41-61 are pending. Claims 52-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 22 February 2006.

Claims 41-51 are examined in this action.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. §119(a)-(d), which papers have been entered. Applicant's provision of foreign priority documents, FRANCE 98/05197, is acknowledged.

Sequence Compliance

The specification and claim 46 are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. Specifically, claim 46 refers to Figure 11 in the specification for a list of sequences not identified by SEQ ID NO. See 37 CFR § 1.821(d). Full compliance is required in response to this Office Action. A reply that fails to comply will be considered to be non-responsive and may result in abandonment of this application.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed on 4 June 2004, is attached to the instant Office action.

Claim Objections

Claim 41 is objected to because it refers to the polynucleotide segments by their acronyms, cPPT and CTS, without first identifying them by their full names, respectively the "central polypurine tract" and "central terminator sequence."

Claim 46 is objected to because it refers to compounds identified by reference to a Figure in the specification. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 43 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,682,907 in view of Naldini *et al.* (1996, filed in IDS).

The patented claim 7 differs from the instant claim 43 in that it does not specifically recite an HIV-type retrovirus and instead recites lentiviral origin.

Naldini *et al.* describes HIV as a human lentivirus. See page 11382, left column, last sentence.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to further limit the vector of retroviral origin in the instant claim to the HIV vector of Naldini *et al.* such that the vector is safe, replication-defective and efficient for *in vivo* gene delivery. One having ordinary skill in the art would have been motivated to make such a modification to optimize gene transduction and delivery, as per the teachings of Naldini *et al.*

into the claim." See MPEP § 2173.05(s). It is suggested that the claim be amended to include the SEQ ID NO's disclosed in Figure 11.

Appropriate correction is required.

Double patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 41-51 are rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 3, 4, 8-11, 14, 15, 22, and 23 of prior U.S. Patent No. 6,682,907. This is a double patenting rejection.

Claims 41-51 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3, 4, 9-14, 20, 27, and 33 of copending Application No. 10/313,038. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Claim 41 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,682,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claim 2 recites that the sequences of retroviral origin are derived from a lentivirus genome, which is a species of retrovirus. The instant claim recites retroviral or retroviral-like origin, which is generic to all that are recited in the patent claim 2, that is, patent claim 2 falls entirely within the scope of the instant claim 41. Therefore, the instant claim 41is anticipated by claim 2 of U.S. Patent No. 6,682,907.

Case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim. *In re Berg*, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); *In re Gosteli*, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).

Claims 41 and 51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21 and 23-26 of copending Application No. 10/313,038. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims recite species of the transgene and the recombinant cell. The recitation in the instant claims 41 and 51 are generic to all that are recited in the copending claims 21 and 23-26, in other words, the copending claims fall entirely within the scope of the instant claims.

Therefore, the instant claims 41 and 51 are anticipated by claims 21 and 23-26 of the copending Application No. 10/313,038.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-49 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "a sequence which may be selected from the sequences shown in FIG. 11", the phrase "may be" is non-limiting and renders every following phrase meaningless.

Claims 47 and 49 recite the limitation "the *gag*, *pol*, and *env* sequences" in each line. There is insufficient antecedent basis for this limitation in the base claim 41.

Claim 48 is indefinite because it depends from itself.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-51 are rejected under 35 U.S.C. §102(b) as being anticipated by Verma *et al.* (WO 97/12622, filed in IDS).

The instant invention is a recombinant vector comprising a polynucleotide comprising a cis-acting central initiation region (cPPT) and a cis-acting termination region (CTS), wherein the cPPT and CTS are of retroviral-like origin and derived from a retrotransposon; a defined nucleotide sequence (transgene or sequence of interest); and regulatory signals for reverse transcription, expression, and packaging, wherein said regulatory signals are of retroviral or retroviral-like origin.

Verma *et al.* teaches a recombinant retroviral vector that transduces the target cell nucleus and expresses a transgene of interest (i.e. a gene encoding a reporter protein) in the target cell. Specifically, Verma *et al.* teaches: "The recombinant retrovirus comprises a viral *gag*, a viral ***pol***, a viral *env*, a heterologous nucleic acid sequence operably linked to a regulatory nucleic acid sequence, and cis-acting nucleic acid sequences necessary for packaging, reverse transcription and integration," as described above (emphasis added, see paragraph bridging pages 4 and 5 and first full paragraph on page 5). Verma *et al.* further teaches an HIV-based vector. See Figure 1. Verma *et al.* also teaches *env* genes from retroviruses other than HIV. See page 6, lines 10-14. Further, Verma *et al.* teaches recombinant cells comprising the recombinant retroviral vectors. See page 7, second paragraph.

The cPPT and CTS cis-acting regions are located within the retroviral *pol* gene, which has evolutionary lineages to retrotransposons such as yeast retrotransposons.

Therefore, any retroviral *pol* gene would necessarily have at least one cPPT and at least one CTS cis-acting region that can be derived from a retrotransposon. Furthermore, the cPPT and CTS cis-acting regions play an essential role during reverse transcription of retroviral sequences and induce the formation of a triple-stranded DNA structure comprising the retroviral sequences as well as the newly transcribed strand. As indicated above, Verma *et al.* teaches that the retroviral vector comprises a *pol* gene. Therefore, the vector used by Verma *et al.* has at least one cPPT and at least one cis-acting CTS, which would necessarily induce the formation of a triple-stranded DNA structure during reverse transcription of the vector sequence. Thus, the instant invention is anticipated by Verma *et al.*

Claims 41-48, 50, and 51 are rejected under 35 U.S.C. §102(b) as being anticipated by Parolin *et al.* (1994).

The instant invention is as indicated above.

Parolin *et al.* teaches HIV vectors of cis-acting sequences that affect gene transfer. These vectors have been adapted as suitable vehicles for delivering genes into eukaryotic cells. Specifically, Parolin *et al.* teaches HIV vectors comprising the pol gene (e.g., see p. 3890, Figure 1B), which, as indicated above, includes at least one cPPT and at least one CTS cis-acting region, which would necessarily induce the formation of a triple-stranded DNA structure during reverse transcription of the vector sequence, and which are derived from transposons such as yeast retrotransposons. The transgene of interest is a selectable marker encoding neomycin

phosphotransferease, which is contained in an expression cassette comprising regulatory signals for transcription and expression, HIV *tat* and *vif*, or *rev*. The recombinant HIV vector is then transduced into COS-1 cells to form recombinant cells comprising the vectors (page 3889, Materials and Methods).

Thus, the instant invention is anticipated by Parolin *et al*.

Remarks

No claim is allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
20 March 2006

JEFFREY STUCKER
PRIMARY EXAMINER

John LeGuyader
Director TC 1600